

AUG 21 2002

K022575

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92."

"The assigned 510(k) number is: _____."

1. Submitter Information:

July 31, 2002

B. Braun Medical Inc.
1601 Wallace Drive Ste. 150
Carrollton, TX. 75006
(972) 245-2243 ext. 206

Contact Person: Ms. Linda Morgan
Regulatory Affairs Specialist
Phone: 972.245.2243 ext. 339
FAX: 972.245.1612

2: Name of Device:

Infusion Pump

Trade Name:

Perfusor® compact with *fm* system

Classification Name:

**Class II, 80FRN
21 CFR 880.5725**

3: Predicate Device:

The predicate devices that B. Braun Medical Inc. is claiming substantial equivalence¹ to are the Horizon Outlook™ and the Alaris Medley™ Patient Care System. The Horizon Outlook™ is marketed by B. Braun Medical under cleared 510(k) K994375. The Medley™ Patient Care System is marketed by Alaris under cleared 510(k) 950419. This substantial equivalence claim is intended for Food, Drug and Cosmetic Act purposes only. There are no new issues of safety or effectiveness raised by the Perfusor® compact with *fm* system.

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¹ The term "substantially equivalent" as used herein is intended to be a determination of substantial equivalence from an FDA -regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patent point of view. The term "substantially equivalent" is not applicable to and does not diminish any patent claims related to this product or the technology used to manufacture the product.

4: Description of the Subject Device:

The Perfusor® compact is a battery and AC powered transportable syringe delivery system intended to provide infusion of parenteral and enteral fluids. The addition of the *fm system* will enhance the use of the Perfusor® compact by allowing the user greater flexibility in the administering and monitoring of a patient's infusion status. Used as a complete system the Perfusor® compact with *fm system* introduces some additional features to aid the clinician in fluid delivery and maintenance.

These features include the addition of a barcode reader to minimize the potential for programming errors, an external power source to reduce the number of electrical outlets required at the bedside, and the convenience of a large interactive monitor that displays the status of all Perfusor compacts being used on one particular patient. This monitor also incorporates the use of a drug library, makes calculations based on user input. In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, B. Braun Inc. intends to introduce into interstate commerce the Perfusor® compact with *fm system*.

The infusion pump contains the following hardware assemblies: swivel-drive pumping mechanism assembly, power supply assembly, pole clamp assembly, display assembly, and electronics assembly. The power supply cord can be mounted and removed from a receptacle in the rear of the pump. The battery power supply consists of four AA alkaline batteries. The display subassembly contains an LCD display and a keypad used to input data into the pump as well as to present pump status and information to the user.

The electronics subassembly contains all of the electronics in the pump, including the microprocessors that run the software. The electronics subassembly also contains communications electronics that will allow the pump to transmit and receive messages to and from external devices, including personal computers and hospital monitoring systems.

The software provides communication capabilities from the pump to external communication devices. This includes transmission of the following information: Operation / Alarm Log, pump status and pump configuration / calibration data.

The software also provides communication abilities from external devices to the pump. This feature is only accessible by a trained Biomedical Technician. Programming of the pump is to be performed by trained Biomedical professionals.

5: Intended Use of the Subject Device:

The intended use of the Perfusor® compact with *fm system* remains to provide accurate and continuous flow of parenteral, including blood, and enteral fluids to the patient. The addition of the *fm system* extends the abilities of the Perfusor® compact and creates a versatile system that will enhance the administration and management of infusion therapy. The *fm system* may be used in a variety of configurations depending on the level of needs of the healthcare facility.

The new incorporation of a barcode reader and programmable dosing limits are intended to aid in medication error reduction by decreasing the steps necessary to program an infusion and to alert the clinician when dose amounts are not within facility defined parameters.

The Perfusor® compact with *fm system* is intended for but not limited to use in the hospital and/or other healthcare facilities. The Operation Manual is intended to reinforce the teaching given to the user by a trained healthcare professional or an authorized B. Braun Medical Inc. representative. A trained Biomedical Technician must perform a full set-up of the pump before use in a clinical setting.

6: Technological Characteristics of the Subject Device

The subject device, Perfusor® compact with *fm system* is substantially equivalent to the predicate devices, the Horizon Outlook™ and the Alaris Medley™ Patient Care System. The subject and predicate devices are similar in design, material composition, components, manufacturing process, intended use and labeling. There are technological differences between the subject and predicate device, however, these differences do not raise new issues of safety and effectiveness. The substantial equivalence claim between the subject and predicate device is supported by the information and data provided in this 510(k) submission. This includes the following information:

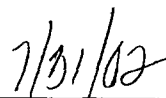
- Description of the subject and predicate devices.
- Intended use of the subject and predicate devices.
- Material composition of the subject and predicate devices.
- Labels and labeling for the subject and predicate devices.

- Comparison tables of attributes and specifications of the subject and predicate devices.
- Subject device customer functional specification.
- Subject device system and software hazard analysis.
- Subject device system and software requirements.
- Subject device system and software test plans.
- Subject device system and software trace matrix.

7: Signature of Applicant

B. Braun Medical Inc.
Linda Morgan RN, BSN
Regulatory Affairs Specialist


Signature


Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2002

Ms. Linda Morgan
Regulatory Affairs Specialist
B. Braun Medical, Incorporated
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Re: K022575

Trade/Device Name: Perfusor® Compact with FM System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: July 31, 2002
Received: August 2, 2002

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

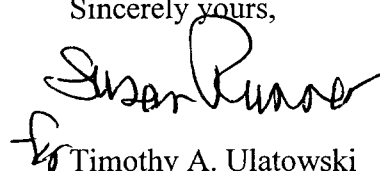
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", is written over the typed name.

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known)

Device Name: Perfusor® compact with *fm system*

Indications For Use:

The intended use of the Perfusor® compact with *fm system* is to provide accurate and continuous flow of parenteral, including blood, and enteral fluids to the patient. The addition of the *fm system* extends the abilities of the Perfusor® compact and creates a versatile system that will enhance the administration and management of infusion therapy. The *fm system* may be used in a variety of configurations depending on the level of needs of the healthcare facility.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Patricia Cucurite
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: 14022575

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